

Evaluation, Findings, and Recommendations  
of the online recertification process for clients of the  
Federal AIDS Drug Assistance Program (ADAP)  
through the Florida Department of Health

Investigator:

BRIAN A. SMITH, D.C. (*ret*)

Orlando, Florida

March 2019

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March 29, 2019

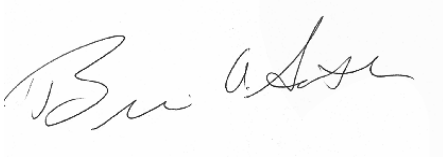
Re: Florida Department of Health's online ADAP recertification program – and investigation

You have been designated as a Recipient for the results of a study conducted to evaluate the online option for ADAP Re-Certification of the State of Florida, Department of Health.

This evaluation was conducted over the course of two month in the first quarter of 2019 without the knowledge of any party other than the requesting party, the subject, and the investigator.

A synopsis of the RECOMMENDATION is on the first page.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brian A. Smith", is written over a light gray rectangular background.

Dr. Brian A. Smith (ret)

Florida Department of Health's online ADAP recertification program – and investigation

Investigator: Dr. Brian A. Smith (ret)

Summary

The investigator was engaged to evaluate the effectiveness of the online ADAP recertification program that was introduced to Floridians by the Florida Department of Health, hereinafter FL DoH. The program is operated with input from the *FL DoH HIV/AIDS Section Workgroup for the Florida AIDS Drug Assistance Program (ADAP)*. Information about the program is posted at the Florida Health page under Diseases and Conditions>AIDS>ADAP at <http://www.floridahealth.gov/diseases-and-conditions/aids/adap/index.html>. There is no mention of the online recertification process on this page or in any of the links. Access to the page for recertification is through a different Florida Health domain (<https://flhealth.providecm.net>). Many States have had a similar online process available for approximately 20 years; Florida's program was in the test phase in June 2017.

The investigator was on the committee that wrote the original bill (HR 4785 - AIDS Prevention Act) submitted by House Representative Henry Waxman in 1989 that became the *Ryan White Comprehensive AIDS Resources Emergency Act of 1990*. He has been involved with several EMAs in California, New Jersey, and Pennsylvania and most recently Orlando. The Orange County Health Department pharmacy provides ADAP prescriptions to over 10% of the total persons enrolled in the program (2785/26120).

Criteria

The subject met the following criteria which were established to make the recertification process as simple as possible:

1. At least a three (3) year history of ADAP eligibility in this State.
2. No significant changes to report for recertification.
3. There was a minimum of fourteen days between the date the online recertification process was started and the date of expiration of their ADAP eligibility.

The following recommendation is based solely on the evaluation and the possible consequences to clients. A discussion can be found at the end of the evaluation.

Recommendations:

1. Immediate suspension of ADAP online recertification program followed up by investigation as to causes of the several failures noted in the evaluation. Clients are being put at risk of disease progression by this program.

### Event chronology

A condition of participation was the subject had to have access to the prescription medications required to maintain full viral suppression outside of the ADAP program. This was to prevent a lapse in the ARV regimen in case the system failed to complete the task for which it was created.

This description of events begins the day before the online recertification process was initiated and ends when the subject had the prescription from the ADAP pharmacy in their possession. The investigator was present when the subject accessed the State's website recertification process for every date that is made part of this evaluation. The investigator verified all telephone and text contact by a review of the subject's mobile phone logs when such contact was not made in his presence. A complete chronology of the events during the recertification process in calendar form is found in Appendix 1: Chronology of Events

Subject obtained the "Notice of Eligibility" from the non-medical case manager 17 days prior to the expiration of their ADAP eligibility period.

Subject initiated and completed the online ADAP recertification process the following day, designated "Day 0." Three items were uploaded during the initial submission process:

1. The aforementioned "Notice of Eligibility" signed by the nonmedical case manager.
2. Laboratory results dated 20 days earlier.
3. A 3-month prescription for antiretroviral therapy (ARV) dated 36 days earlier.

When completed, the following message was returned from the State: *Successfully submitted*. Subject received the following message when checking the status on days 6, 9, 14, 17, and 28:

*Your Eligibility Assessment is being worked. If you have questions please contact your local County Health Department ADAP Office for help.* (Appendix 2)

Between Day 0 and Day 23 the subject was not contacted by the State regarding the status or additional information required to process the application.

Subject called ADAP Manager (hereinafter AM) on Day 8 which was 8 days before ADAP eligibility period ended. Numerous calls were made (*see Appendix 1*) but there was never any direct contact made by the AM. An appointment was scheduled on Day 23, which was 7 days *after* ADAP eligibility period expired and over two weeks since initial contact was made. During that meeting, the AM called "Tallahassee" and was told that eligibility had expired because "*laboratory results and current prescription were not submitted.*" AM confirmed to subject that lab results were "in the [computer] system" at least 7 days before Day 0 and Tallahassee had access to them all along. The ARV prescription was sent again and AM received confirmation of eligibility. The pharmacy was out-of-stock of subject's ARV and it would not be available until Day 27 due to reduction in the days of operation of the pharmacy.

Subject contacted pharmacy on Day 27 and was informed that the State is still showing the subject as ineligible for ADAP benefits on their computer system, 4 days after eligibility was confirmed by telephone. Eligibility was updated by the State on Day 28 and subject was able to pick up ARV on Day 29. Subject was out of ARV medication (if the aforementioned provisions had not been made) for a total of 13 days.

Investigator contacted the FL DoH on the 6<sup>th</sup> of March at which time the State was made aware that an evaluation of the recertification process was currently underway. The State was given the option to participate in the evaluation through a request made to the ADAP Section Administrator and the ADAP Data Integration Team leader. Investigator received confirmation on the following day that both had received the communication. The State has not made contact and has not participated in this evaluation (*Appendix 3*).

#### Discussion and Recommendations:

Interruptions of ARV drug regimens have consistently shown to have negatively impacts on the health outcomes of HIV+ patients. The investigator has reason to believe, through contact with several clients of the OCHD pharmacy, that the average client experiences two interruptions of ARV drug regimens per year of varying duration. The average amount of time a client is without prescribed medications is 4 days per episode with 2 episodes each year. The number of clients questioned is not large enough to draw any specific conclusions but does provide the basis for a formal investigation.

Research has demonstrated that when a provider, or system, is inconsistent in providing the prescription medications needed to treat a specific illness or injury, the perception of the patient as it concerns the importance of adherence to a regimen schedule is negatively impacted for the specific medication and for all other prescription medications as well. The result is a greater degree of patient non-compliance. In this evaluation, the direct causative factor is the failure of the FL DoH to implement and maintain a safe and effective online ADAP recertification process.

Given the above research conclusions and the failure of the online system, there exists a high degree of probability that the lives of ADAP clients in Florida have been placed at risk. The only acceptable recommendation is:

1. Immediate suspension of ADAP online recertification program followed up by investigation as to causes of the several failures noted in the evaluation.
  - a. Suggestion: study, evaluate, and adopt a successful ADAP online recertification program that demonstrates a proven track record of providing clients with impeccable service, e.g. Los Angeles.

This is needed to protect the health of the clients of the program. Other States have had an online recertification process available to clients for around 20 years; this is not a new or untested program.

Florida Department of Health may be in violation of Federal law.

The FL DoH adopts rules to regulate client access to ARVs that violate the intent, if not the word, of the *Ryan White Comprehensive AIDS Resources Emergency Act of 1990*. The law did not allow for States to withhold approved medications once eligibility was established and there have been no substantial changes to that up through the *Ryan White HIV/AIDS Treatment Extension Act of 2009*. This clause was specifically included to prevent a State from interfering with the delivery of prescription medications to clients. The State is contravening the law in the following manner:

- FL DoH will suspend prescription refills for any client who is eligible for ADAP for 6 months if, at any point in that 6-month period, there is not laboratory work consisting of an immune panel and HIV assay on file with them that is less than 6-months old. The law holds that once a client has been approved, *the State cannot deny access* to their prescribed medications during that 6-month period.
- FL DoH requires participating pharmacies to obtain monthly approval by ADAP for every prescription filled – despite the 6-month eligibility status.
- FL DoH requires that clients do not receive a prescription refill more than 4 days before the date the last prescription supply runs out. OCHD pharmacy is closed for 3 consecutive days every week. With the time required for the pharmacy to obtain the approval from the ADAP department varying from 4 to 10 days, it is not possible to refill the prescription(s) required every month of the year.

Additional recommendations due to the above:

Florida Department of Health:

1. Outside review and assessment of procedures, including outcomes, of all Ryan White funded programs with assessment of possible impediments to obtaining prescribed medications, and correction thereof, so as to no longer endanger the life of their clients.
2. Outside evaluation of all rules and regulations and determine their alignment with, or violation of, Federal law, especially enshrined by the *Ryan White HIV/AIDS Treatment Extension Act of 2009*. Any rule or regulation that impedes the Federal mandate is repealed. Until such time that appropriate procedures and policies are adopted, there is to be no penalization of any client of a Ryan White funded program.
3. The FL DoH has established a *de facto* policy that violates Federal law inasmuch as the refusal to fill a 3-month prescription is not in the Federal legislation covering such requests. The ADAP Operations Manager stated in June 2017 that a 90-day supply of medications is available to clients that meet the established criteria. As of the date of this evaluation the OCHD pharmacy has stated that they have never received an approval

from the State for such a request. Treating physicians have made the same statement to the investigator. The State is prohibited from establishing any policy or adopting any procedure, rule, regulation, or by any other way, that narrows the word and the intent of the supervening Federal law. The State is to enact policies similar to those they implied had already been enacted during the June 2017 meeting with the *HIV/AIDS Section Workgroup for the Florida AIDS Drug Assistance Program*. All requests are to be conditionally approved as the request itself is understood to implicitly state that all requirements have been met. The State has 30 days to obtain any information necessary to support a denial of request. The State must notify the client within 45 days of receiving the request if they have denied it. The notification will include copies of all documents used in making said determination. The notification will also include the steps required for the client to appeal the denial. Requests that are approved do not require any further action. All requests are unconditionally approved after 30 days from the date of receipt of the request if no determination of denial has been documented.

The data collected to make this evaluation and this evaluation is the property of the investigator. All parties with an interest in the program evaluated such as private law firms, regulatory agencies, news media outlets, et cetera, can submit requests to use or disseminate this evaluation to the investigator at the address below. The investigator retains all rights to grant or deny any requests and has no obligation to inform the requesting party of the decision.

Submitted this 29<sup>th</sup> day of March, 2019.



Dr. Brian A. Smith (ret)

Please address all requests for Dr. Smith to: [redacted], Orlando, Florida 32828

**NOTICE:** The right to all data, evaluation, and discussion in this report remain the private property of the investigator and is protected by copyright. Do not copy or cause to be disseminated, by any method this evaluation, or any portion thereof, without requesting and obtaining approval from the author.

## APPENDICES

APPENDIX 1: CHRONOLOGY OF EVENTS

APPENDIX 2: RESPONSES RECEIVED FROM FLORIDA DEPARTMENT OF HEALTH

APPENDIX 3: COMMUNICATIONS WITH FLORIDA DEPARTMENT OF HEALTH ON 6 & 7 MARCH



## APPENDIX 1: CHRONOLOGY OF EVENTS

|    |  |    |  |    |   |    |   |    |                     |    |                     |    |                     |
|----|--|----|--|----|---|----|---|----|---------------------|----|---------------------|----|---------------------|
| -1 | Notice of Eligibilty obtained from non-med case mgr        | 0  | Recert:<br>A -labs<br>D -Rx<br>A -Residen<br>A -Income<br>A -Notice<br>P Success | 1  |   | 2  |   | 3  |                     | 4  |                     | 5  |                     |
| 6  | Yellow days = checked status online – NO CHANGE            | 7  |  | 8  | Called ADAP M twice - Told “ADAP expires next week”         | 9  | ADAP M called; disconnected. Called ADAP M twice                          | 10 |                     | 11 |                     | 12 |                     |
| 13 |  | 14 |  | 15 | Called twice. Told “ADAP exp next day. Out of meds 2 days.” | 16 | ADAP Eligibilty <b>ENDS</b> Called twice; “Out of meds today.”            | 17 |                     | 18 |                     | 19 |                     |
| 20 | Called Pharm: ADAP status Ineligible<br><br>Txt: OCHD appt | 21 |  | 22 |   | 23 | Recert done. See EVAL.<br><br>11 a m<br><br><b>Pharm out-of-stock ARV</b> | 24 | <b>Pharm CLOSED</b> | 25 | <b>Pharm CLOSED</b> | 26 | <b>Pharm CLOSED</b> |
| 27 | Pharm: <b>ADAP Ineligible</b><br><br><b>No Rx</b>          | 28 | Pharm: <b>ADAP Eligible</b><br><br>Rx pick up next day                           | 29 | Pick up Rx; restart.<br><br><b>End 12 day w/o ARV</b>       | 30 |   | 31 |                     | 32 |                     | 33 |                     |

From **Day 16 through Day 28**, subject did not have ARV medication obtained through ADAP.

On **Days 6, 9, 14, 17, and 28**, subject checked status, receiving reply as stated in body.

## Evaluation of the Florida Department of Health online ADAP recertification process

### APPENDIX 2: RESPONSE RECEIVED FROM FLORIDA DEPARTMENT OF HEALTH



#### *It's a New Day in Public Health.*

The Florida Department of Health works to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

#### Six-month Recertification Submission Successful

Your Six-month Recertification has been successfully submitted. Your confirmation code is [REDACTED]

Please print and keep a copy of this page for future reference. Your Six-month Recertification has been submitted but it appears to be missing the following documentation:

- Proof of Residency
- Proof of Income

You have 45 business days to submit all the missing documentation listed above.

[Print](#)[Home](#)

[REDACTED] 26



#### *It's a New Day in Public Health.*

The Florida Department of Health works to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

#### Assessment Status

Your Eligibility Assessment is being worked. If you have questions please contact your local County Health Department ADAP Office for help.

[Home](#)

[REDACTED] 32

Florida Dept

APPENDIX 3: COMMUNICATIONS WITH FLORIDA DEPARTMENT OF HEALTH ON 6 & 7 MARCH

From: Brian Smith, DC [mailto:briansmithdc@aol.com]  
Sent: Thursday, March 7, 2019 12:42 PM  
To: zzzz Feedback, Health <Health@flhealth.gov>  
Subject: Attn: Laura Reeves, Melinda Waters

*To: Laura Reeves, Section Administrator  
To: Melinda Waters, Data Integration Team*

*I am evaluating the online ADAP Recertification process recently started by the Florida Department of Health and I am giving you the opportunity to have your response(s) to questions regarding (1) the process itself and (2) the response of your office that clients may expect to receive included as part of my final report.*

*Please contact me by return e-mail so my questions can be submitted to you directly for your response. The questions will be included with the report as part of the evaluation process.*

*My report will be submitted on April 1st and I will be glad to send you a copy of my findings.*

*Respectfully,*

*Dr. Brian A. Smith*

From: zzzz Feedback, Health Health@flhealth.gov  
To: Brian Smith, DC briansmithdc@aol.com  
Cc: Reeves, Laura Laura.Reeves@flhealth.gov,  
Waters, Melinda Melinda.Waters@flhealth.gov

Thu, Mar 7, 2019 12:48 pm

*Thank you for writing to the Department of Health. Your email has been forwarded to Laura Reeves and Melinda Waters as requested.*

**Florida Department of Health**

*OUR MISSION*

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

**NOTE:**

Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your email communication may therefore be subject to public disclosure.